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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/026,331	12/21/2001	Yasumichi Hitoshi	021044-001310US	8086

20350 7590 12/15/2004

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EXAMINER	
AKHAVAN, RAMIN	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/026,331	HITOSHI ET AL.	
	Examiner	Art Unit	
	Ramin (Ray) Akhavan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-52 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-52* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-52 are pending and under consideration in this action. Receipt is acknowledged of a substitute computer readable form (CRF), filed 08/10/2004.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121 (as indicated by the following Roman numerals):

I. Claims 1-7, drawn to a method of identifying a compound capable of interfering with binding of an MRE11 polypeptide, designated in class 435, subclass 7.8.

II. Claims 8-41, drawn to a method of identifying a compound that modulates cellular proliferation or chemosensitivity, designated in class 435, subclass 7.21.

III. Claims 42-45, drawn to a method of modulating cellular proliferation in a subject using an antibody, designated in class 424, subclass 178.1.

IV. Claims 42 and 46, drawn to a method of modulating cellular proliferation in a subject using antisense, designated in class 536, subclass 24.5.

V. Claims 42, 47 and 50, drawn to a method of modulating cellular proliferation in a subject using a small organic molecule, designated in class 424, subclass 278.1.

VI. Claims 42, 48-49 and 51, drawn to a method of modulating cellular proliferation in a subject by administering a peptide, designated in class 424, subclass 185.1.

VII. Claim 52 drawn to a method of modulating cellular proliferation in a subject by administering a nucleic acid, designated in class 514, subclass 44.

The claims encompass seven separate inventions. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Each of the inventions (Groups I-VII) is drawn to a biologically and patentably distinct outcome/effect. Furthermore, the inventions are not necessarily capable of use together. As such, a search for one invention would not necessarily be co-extensive for another invention.

It should be noted that claim 42 is a linking claim, which links the inventions of Groups III-VI. The restriction requirement for the linked inventions is subject to the nonallowance of the linking claim. Upon the allowance of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claim will be entitled to examination in the instant application. Applicant is advised that if any such claims depending from or including all the limitations of the allowable linking claims are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group I is directed to identification of a compound that interferes with MRE11 binding (protein of SEQ ID NO:2). Therefore, a compound so identified would at least on some level interfere with binding. Biologically and functionally, merely binding a protein would not necessarily translate into an identified downstream functionality (e.g. modulating cellular proliferation).

In other words, the process's outcome is to identify a protein-binding compound, but such a compound is not necessarily a modulator of cellular proliferation (e.g. *in vitro* use), or a compound capable of *in vivo* application in a subject. Therefore, this invention is not necessarily capable of use with any of the other inventions. Furthermore, because the outcome or effect for this process is distinguishable, a literature search for this invention would not necessarily be co-extensive with the remaining inventions, each of which will be described in the proceeding discussion.

Group II is directed to a method of identifying a compound that is a modulator of cellular proliferation or chemosensitivity, through interaction of the compound with MRE11 protein (SEQ ID NO:2). Again, for reasons mentioned in the foregoing paragraph, such a process is biologically and patentably distinct from the other inventions. Irrespective of binding or the level of binding, the process's outcome is to identify a compound with a particular functionality, which is distinguishable from merely affecting binding. As such, the process is directed to a materially different effect/outcome.

Generally, methods drawn to *in vivo* applications are considered biologically and materially different inventions as to compared to other methods. Furthermore, as *in vivo* applications involve complex interactions, elements or factors (e.g. immune system involvement, target delivery, unintended adverse effects, etc.), particular critical elements that comprise a method can each require additional consideration or search.

That being said, Group III is drawn to a specific area of biomedicine. More particularly, the process comprises critical elements directed to *in vivo* therapy using an antibody. No other group involves such elements, thus this invention would not necessarily be capable of use with the other inventions. Here, the means for obtaining the objective of modulating cellular proliferation is materially different from any of the other inventions.

Group IV is directed to another distinct area of biomedicine – antisense therapy. The vagaries for antisense therapy are distinct and particular (e.g. degradation within/without the cell, potential for random integration, non-target effects), thus not relevant to any of the other inventions. As such, a search in the relevant art would not be co-extensive with any of the other inventions.

Group V is directed to modulating cellular proliferation *in vivo* using small organic molecules. This method is materially different based on the limitation of "small organic molecules". Each particular molecule could pose attendant concerns of patentability (e.g. toxicity, delivery, dosage or dose-response), which would in turn entail a separate and burdensome search, considering the scope of the invention.

Group VI is directed to *in vivo* therapy using peptides, which in turn entail attendant biological and chemical concerns specific for using peptides in a subject (e.g. immunotoxicity, secondary/tertiary folding under biological conditions, dosage, etc.) and which would be particular to each individual peptide as well. No other group is directed to *in vivo* application of peptides, thus this invention entails a materially different process.

Finally, Group VII is directed to *in vivo* application using nucleic acids generally, which for example, reads on naked DNA administration or vector administration. Irrespective of how nucleic acids are characterized, such a process is biologically and patentably distinct as compared to the other inventions. The process encompasses elements/factors that would be searched and considered specifically for this invention (e.g. cell delivery, cell uptake, expression levels, host immune response to expression or vector DNA, etc.).

In sum, each of the inventions, Groups I-VII, is directed to a biologically, materially and patentably distinct process, which would not necessarily be capable of use together. For the reasons given above these inventions are distinct, have acquired a different classification in the art and would require a separate search, thus restriction for examination purposes as indicated is proper. Applicant is advised that a reply to this restriction requirement must include an election for the invention (e.g. Group I, II or III, etc.) to be examined, for the reply to be complete, notwithstanding that the requirement be traversed (37 CFR 1.143). Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if none or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanies by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

The claims are subject to a restriction requirement.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ramin (Ray) Akhavan whose telephone number is 571-272-0766. The examiner can normally be reached on Monday- Friday from 8:00-4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ray Akhavan/AU 1636

GERRY LEFFERS
PRIMARY EXAMINER